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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/488,103	01/20/2000	Paul Stark	7453-0006-00	3945

22852 7590 09/10/2002

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EXAMINER

JOYNES, ROBERT M

ART UNIT PAPER NUMBER

1615

DATE MAILED: 09/10/2002 *ll*

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/488,103

Applicant(s)

STARK ET AL.

Examiner

Robert M. Joynes

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-8,10-25 and 28-42 is/are pending in the application.
- 4a) Of the above claim(s) 2,9,26 and 27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-8,10-25 and 28-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- ☐ Interview Summary (PTO-413) Paper No(s). _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Receipt is acknowledged of applicants' Request for Continued Examination, Information Disclosure Statement and Amendment filed on June 20, 2002.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3-8, 10-25 and 28-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oshlack et al. (US 5580578) in combination with Miller et al. (US 5891471). Oshlack teaches a sustained release formulation wherein a core of an active agent is coated with sustained release polymer coating (Col. 3, lines 1-12). The coating polymer is a copolymer of acrylic and methacrylic esters with a low content of quaternary ammonium groups (Col. 9, lines 30-62). These polymers can be pH dependent or independent (Col. 9, line 63 – Col. 10, line 26). The coating can further contain pore formers (Col. 10, line 35 – Col. 11, line 44), plasticizers (Col. 12, line 27 –

Col. 13, line 23) and talc (Col. 13, lines 24-26). Suitable plasticizers include polyethylene glycols (Col. 13, lines 13-23). The cores can be coated with a barrier layer prior to the sustained release coating to separate the therapeutic active agent from the acrylic coating (Col. 13, lines 62-67). The cores can also be coated with an overcoat after the acrylic polymer coating is applied (Col. 14, lines 35-38). A variety of active agents are contemplated by the reference, including antihypertensives (clonidine, methyldopa) (Col. 16, line 48 – Col. 18, line 11).

Oshlack does not expressly teach the active agent to be bisoprolol or the exact weight percentages ranges for the polymeric coatings.

Miller teaches that clonidine, methyldopa and bisoprolol are known antihypertensive (Col. 2, lines 39-47).

While the reference does not teach the complete concentration or weight percentage range, differences in concentration or weight percentage will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or weight percentage is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to prepare a sustained release composition wherein a core of the active agent bisoprolol is coated with a ammonio methacrylate polymer and optionally coated with a barrier layer and/or an overcoat. It is the position of the Examiner that the

particular salt or enantiomer is not critical to the invention. Any distinction is a matter of degree and not of kind.

One of ordinary skill in the art would have been motivated to do this to provide a composition that provides a therapeutic effect for 24 hours (Oshlack, Col. 4, lines 36-59).

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Applicant's arguments with respect to claims 1, 3-8, 10-25 and 28-30 have been considered but are moot in view of the new ground(s) of rejection.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Joynes whose telephone number is (703) 308-8869. The examiner can normally be reached on Monday through Friday 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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